

I-ONE TECHNICAL SHEET

TYPE	Medical device for the treatment of inflammatory and degenerative diseases of tissues
NAME	I-ONE
MANUFACTURER	IGEA S.p.A. 41012 Carpi (MO), Via Parmenide 10/A (ITA), Italy
MODEL	CBA-03
TECHNICAL DATA	
Generator	NiMh battery power supply : 9,6 VDC – 900 mAh Maximum current assumption : 0,200 A Maximum input power : 3 W Device with internal electrical power supply to be charged with specified power supply.
Rechargeable battery	Type: NiMH 9.6VDC/900mAh Code IG8AAA900 (8x1,2VDC/900mAh Size AAA)
External Power Supply	Input power : 100 -240VAC – 50/60Hz Output voltage / current : 18 VDC – 1000 mA
Applied Part	Copper Coil with anallergic, biocompatible PVC cover
Output signal	Impulsive signal with frequency of di 75Hz ± 5% Pulse width = 1100 µsec (± 100µsec) Magnetic field intensity = 1,5 ± 0,3 mT (15 ± 3 Gauss – peak value)
Dimensions	L x W x H = 68 x 95 x 38 mm
Weight	Generator: 100 g; Battery: 154 g; Coil: 130 g
Classification (EN 60601-1)	Class II with Applied Part of Type BF Appliance for continuous use not to be used where there is danger of explosion Appliance with casing having a degree of protection IP22
Classification Directive 93/42	Ila
Standard Compliance	EN 60601-1 (Medical electrical equipment - Part 1: General requirements for basic safety and essential performance); EN 60601-1-2 (Electromagnetic Compatibility); EN 60601-1-6 (Usability); EN 62304 (medical device software); EN 60601-1-11 (Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment); Medical Device Directive 93/42/CEE e Amending Directive 2007/47/EC
Mark	 0051
Environmental conditions of transportation and storage	Atmospheric temperature : -20 to 45 °C Relative humidity : 30 % to 75 % Atmospheric pressure : 700 to 1060 hPa
Environmental conditions of use	Atmospheric temperature : 0 to 40 °C Relative humidity : 30 % to 75 % Atmospheric pressure : 700 to 1060 hPa

